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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,071

02/14/2005

Isa Gokce

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06/01/2006

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

MONDESI, ROBERT B

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/501,071	Applicant(s) GOKCE ET AL.	
	Examiner Robert B. Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a fusion polypeptide for expression in a host cell comprising a TolAIII domain or a functional homologue, fragment, or derivative thereof and a non-TolA polypeptide, wherein the TolAIII domain or functional homologue, fragment, or derivative thereof is located towards the N-terminus of the fusion polypeptide and the non-TolA polypeptide is located towards the C-terminus of the fusion polypeptide.

Group II, claim(s) 14-25 and 30, drawn to a DNA molecule encoding the a fusion polypeptide for expression in a host cell comprising a TolAIII domain or a functional homologue, fragment, or derivative thereof and a non-TolA polypeptide, wherein the TolAIII domain or functional homologue, fragment, or derivative thereof is located towards the N-terminus of the fusion polypeptide and the non-TolA polypeptide is located towards the C-terminus of the fusion polypeptide and a host cell containing the said DNA.

Group III, claim(s) 26-29, drawn to a method of producing a fusion polypeptide wherein the polypeptide is a a fusion polypeptide for expression in a host cell comprising a TolAIII domain or a functional homologue, fragment, or derivative thereof and a non-TolA polypeptide, wherein the TolAIII domain or functional homologue, fragment, or derivative thereof is located towards the N-terminus of the fusion polypeptide and the non-TolA polypeptide is located towards the C-terminus of the fusion polypeptide.

Group IV, claim(s) 31-32, drawn to a method of immobilisation of a non-TolA polypeptide, comprising the step of: binding the fusion polypeptide to a TolA binding polypeptide (e.g. the TolA-recognition site of colicin N or other colicins, the TolA binding region of bacteriophage g3p-D1 protein, or the TolA binding region of TolB or other Tol proteins).

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Group V, claim(s) 33-34, drawn to a method of purification and isolation a the non-TolA polypeptide, comprising the steps of: (i) binding the fusion polypeptide to a TolA binding polypeptide (e.g. the TolA-recognition site of colicin N or other colicins, the TolA binding region of bacteriophage g3p-D1 protein, or the TolA binding region of TolB or other Tol proteins); (ii) cleaving the non-TolA polypeptide from the TolAIII domain or functional homologue, fragment, or derivative thereof using an endopeptidase; and (iii) separating the cleaved non-TolA polypeptide from the TolAIII domain or functional homologue, fragment, or derivative thereof.

Group VI, claim(s) 35, drawn to a method of studying interaction properties of the non-TolA polypeptide or a fusion polypeptide, for example self-interaction, interaction with another molecule, or interaction with a physical stimulus.

Group VII, claim(s) 36, drawn to a method for high expression of a polypeptide as a fusion polypeptide in a host cell, comprising the step of expressing the polypeptide as a fusion polypeptide wherein the fusion polypeptide is a fusion polypeptide for expression in a host cell comprising a TolAIII domain or a functional homologue, fragment, or derivative thereof and a non-TolA polypeptide, wherein the TolAIII domain or functional homologue, fragment, or derivative thereof is located towards the N-terminus of the fusion polypeptide and the non-TolA polypeptide is located towards the C-terminus of the fusion polypeptide in a host cell.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-VII appears to be that that all relate to a fusion polypeptide for expression in a host cell comprising a TolAIII domain or a functional homologue, fragment, or derivative thereof and a non-TolA polypeptide, wherein the TolAIII domain or functional homologue, fragment, or derivative thereof is located towards the N-terminus of the fusion polypeptide and the non-TolA polypeptide is located towards the C-terminus of the fusion polypeptide.

However, WO 01/21817A (Cited in the IDS filed October 14, 2004) discloses a fusion polypeptide for expression in a host cell comprising a TolAIII domain and a non-

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TolA polypeptide, wherein the TolAIII domain is located towards the N-terminus of the fusion polypeptide and the non-TolA polypeptide is located towards the C-terminus of the fusion polypeptide (e.g. page 7, line 26 to page 8, line 8). D2 discloses methods to produce said fusion polypeptide, use of said fusion polypeptide to isolate or to study the interaction property of the non-TolA polypeptide (e.g. page 7-8); therefore the technical feature linking the inventions of Groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi



OS-191-06